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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

LOREEN NIEWENHUIS,  
Derivatively on Behalf of Nominal  
Defendant AQUESTIVE  
THERAPEUTICS, INC.,

Plaintiff,

v.

KEITH J. KENDALL, JOHN T.  
MAXWELL, DANIEL BARBER,  
DOUGLAS K. BRATTON,  
GREGORY B. BROWN, JOHN  
COCHRAN, SANTO COSTA,  
NANCY S. LURKER, and JAMES S.  
SCIBETTA

Defendants,

and

AQUESTIVE THERAPEUTICS,  
INC.,

Nominal  
Defendant.

Case No.:

**VERIFIED SHAREHOLDER  
DERIVATIVE COMPLAINT**

**JURY TRIAL DEMANDED**

Plaintiff Loreen Niewenhuis (“Plaintiff”) brings this derivative complaint for the benefit of nominal defendant, Aquestive Therapeutics, Inc. (“Aquestive” or the “Company”), against certain members of its Board of Directors (the “Board”) and certain of its executive officers (collectively the “Defendants”) seeking to remedy certain Defendants’ breaches of fiduciary duties and contribution for violations of §10(b) of the Securities Exchange Act of 1934 (the “Exchange Act”). Plaintiff’s allegations are based upon her personal knowledge as to herself and her own acts, and upon information and belief, developed from the investigation and analysis by Plaintiff’s counsel, including a review of publicly available information, filings by Aquestive with the U.S. Securities and Exchange Commission (“SEC”), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record.

## **I. NATURE OF THIS ACTION**

1. Aquestive is a pharmaceutical company that develops and commercializes products using its proprietary PharmFilm technology, which enables the delivery of active pharmaceutical ingredients via a film administered orally. The Company’s business strategy involves creating products that deliver an existing, active pharmaceutical ingredient using less difficult, invasive, or inconvenient means than traditional treatments.

2. Aquestive's future revenues depended on Libervant, which used the active pharmaceutical ingredient diazepam to treat epileptic cluster seizures. The existing diazepam-based treatment, Diastat, was administered rectally, which was problematic for patients. Aquestive proposed to deliver the same active pharmaceutical ingredient through the mouth with PharmFilm. If approved, Libervant would have market exclusivity for seven years and could generate up to \$300 million annually, or about 4 times as much as it made in recent years.

3. In December 2019, Aquestive submitted its New Drug Application ("NDA") for Libervant to the U.S. Food and Drug Administration ("FDA"). One of the clinical studies supporting the NDA was a crossover study aiming to show that Libervant was as effective as Diastat in delivering diazepam to patients. The Company repeatedly stated that the crossover study had demonstrated that Libervant was "comparable" to Diastat and had "confirmed [the] dosing algorithm."

4. However, unbeknownst to stockholders, the crossover study showed that for nearly one in five patients, Libervant was only half as effective as Diastat, presenting a substantial risk that the NDA would not be approved.

5. On September 25, 2020, Aquestive announced that the FDA had issued a Complete Response Letter ("CRL") rejecting Libervant's NDA because 18% of patients showed blood concentrations of diazepam that were "too low" when compared to Diastat. Aquestive's stock price fell by 34% in one day.

6. These revelations precipitated the filing of a securities class action in this District against Aquestive and certain of Defendants, *Lewakowski v. Aquestive Therapeutics, Inc., et al.*, Case No. 3:21-cv-03751-BRM-DEA (the “Securities Class Action”).

7. At least half of Aquestive’s current Board is not disinterested and independent and/or faces a substantial likelihood of liability in connection with the wrongdoing detailed herein. The Board is currently composed of eight members, six of whom are named in this action. As alleged herein, Aquestive’s Chief Executive Officer and director knowingly issued misleading statements touting the results of the crossover study. Moreover, after “positive topline results” were announced, the Board caused Aquestive to slow the regulatory approval of the Company’s key competitor, suggesting that the Individual Defendants knew or should have known that the crossover study failed to demonstrate equivalence to support regulatory approval of the Libervant NDA. Thus, more than half the members would be interested in a demand to investigate their own wrongdoing.

## **II. JURISDICTION AND VENUE**

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 in that this Complaint states a federal question: violations of Section 10(b) of the Securities Exchange Act of 1934. This Court has supplemental jurisdiction over the state law claims asserted herein pursuant to 28 U.S.C. § 1367(a). This action is not

a collusive one to confer jurisdiction on a court of the United States which it would not otherwise have.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1401 because a substantial portion of the transactions and wrongs complained of herein occurred in this District, and the Individual Defendants have received substantial compensation in this district by engaging in numerous activities that had an effect in this District.

### **III. PARTIES**

#### **Plaintiff**

10. Plaintiff Loreen Niewenhuis purchased 3,074 shares of Aquestive between May 5, 2020, and July 16, 2020 and has continuously owned Aquestive stock since May 2020.

#### **Nominal Defendant**

11. Nominal Defendant Aquestive Therapeutics, Inc. (“Aquestive” or the “Company”) is incorporated under the laws of Delaware and its principal executive offices are at 30 Technology Drive, Warren, New Jersey 07059. Aquestive’s common stock trades on the NASDAQ exchange under the symbol “AQST.”

#### **Defendants**

12. Defendant Keith J. Kendall (“Kendall”) has served as Chief Executive Officer, President, and a director of the Company since November 2014. Prior to that, he served as Chief Operating Officer from November 2011 to November 2014

and as Chief Financial Officer from 2006 to 2011. Kendall was a member of the Disclosure Committee at all relevant times. He is named as a defendant in the Securities Class Action.

13. Defendant John T. Maxwell (“Maxwell”) served as Chief Financial Officer (“CFO”) and Senior Vice President of the Company- from January 2017 until December 2020. He is named as a defendant in the Securities Class Action.

14. Defendant Daniel Barber (“Barber”) has served as Aquestive’s Chief Operating Officer since April 2019. From 2014 through April 2019, Barber served as Aquestive’s SVP – Chief Strategy & Development Officer. He is named as a defendant in the Securities Class Action.

15. Douglas K. Bratton (“Bratton”) has served as a director of the Company from January 2004 to February 2021.

16. Defendant Gregory B. Brown, M.D. (“Brown”) has served as a director of the Company since March 2007. He was a member of the Disclosure Committee at all relevant times and was a member of the Audit Committee until February 2021.

17. Defendant John Cochran (“Cochran”) has served as a director of the Company since January 2004. He is a member of the Disclosure Committee at all relevant times.

18. Defendant Santo Costa (“Costa”) has served as a director of the Company since December 2015.

19. Defendant Nancy S. Lurker (“Lurker”) has served as a director of the Company since April 2018. She served as a member of the Audit and Disclosure Committees at all relevant times.

20. Defendant James S. Scibetta (“Scibetta”) has served as a director of the Company since April 2017. He was Chair of the Audit Committee and a member of the Disclosure Committee at all relevant times.

21. Defendants Kendall, Maxwell, Barber, Bratton, Brown, Cochran, Costa, Lurker, and Scibetta are collectively referred to as the “Individual Defendants.”

#### **Relevant Non-Parties**

22. Julie Krop (“Krop”) has served as a director of the Company since February 2021.

23. Marco Taglietti (“Taglietti”) has served as a director of the Company since February 2021.

### **IV. DUTIES OF THE INDIVIDUAL DEFENDANTS**

#### **A. Fiduciary Duties**

24. By reason of their positions as officers, directors, and/or fiduciaries of Aquestive and because of their ability to control the business and corporate affairs of Aquestive, at all relevant times, the Individual Defendants owed Aquestive and its shareholders fiduciary obligations of good faith, loyalty, and candor, and were required to use their utmost ability to control and manage Aquestive in a fair, just,

honest, and equitable manner. The Individual Defendants were required to act in furtherance of the best interests of Aquestive and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit. Each director and officer of the Company owes to Aquestive and its shareholders a fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

25. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Aquestive, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. Because of their advisory, executive, managerial, and directorial positions with Aquestive, each of the Individual Defendants had knowledge of material non-public information regarding the Company.

26. To discharge their duties, the officers and directors of Aquestive were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of Aquestive were required to, among other things:

- (a) Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of the business;



- (b) Exercise good faith to ensure that the Company was operated in a diligent, honest, and prudent manner and complied with all applicable federal and state laws, rules, regulations and requirements, and all contractual obligations, including acting only within the scope of its legal authority;
- (c) Exercise good faith to ensure that the Company's communications with the public and with shareholders are made with due candor in a timely and complete fashion; and
- (d) When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

**B. Disclosure Committee**

27. In October 2019, the Board established a Disclosure Committee as part of its authority to “establish other committees to facilitate the management of our business.” According to the Company's proxy statements, the Disclosure Committee “provides advice with respect to the public disclosures made by the Company to the SEC and the Company's stockholders.” The committee does not have a written charter.

**C. Audit Committee**

28. The Audit Committee Charter provides that members “assist[] the Board in monitoring . . . (3) the effectiveness of the Company's internal controls, (4) the performance of the Company's internal audit function, [and] (5) the Company's financial risk management process.”

29. The charter specifically stated that the Audit Committee shall “[r]eview and discuss with management the Company’s major financial risk exposures and the steps management has taken to monitor and control such exposures, including the Company’s financial risk assessment and financial risk management policies.”

## **V. SUBSTANTIVE ALLEGATIONS**

### **A. Background**

30. Aquestive is a pharmaceutical company that develops and commercializes products using its proprietary PharmFilm technology, which enables the delivery of active pharmaceutical ingredients via a film administered orally.

31. The Company’s business strategy involves creating products that deliver an existing, active pharmaceutical ingredient using less difficult, invasive, or inconvenient means than traditional treatments. Specifically, the Orphan Drug Act grants exclusivity to certain drugs that prohibits approval of any other drug using the same moiety (i.e., active pharmaceutical ingredient) for the same indication for seven years. Though such exclusivity is typically reserved for conditions that have no approved treatment, the orphan drug designation is also given to drugs that provide “a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care.” 21 USC § 360cc(c)(2). A “major contribution to patient care” can include a better method of administration, for which the FDA

considers: “convenient treatment location; duration of treatment; patient comfort; reduced treatment burden; advances in ease and comfort of drug administration; longer periods between doses; and potential for self-administration.” By obtaining orphan drug designation for its products, Aquestive could obtain 7-year exclusivity for delivering an existing treatment orally via PharmFilm.

32. Though it has five products, Aquestive derives 57% of its total revenues from the sales of its largest commercialized licensed product, Suboxone, a formulation of buprenorphine and naloxone to treat withdrawal symptoms while inhibiting the high that spurs patients to abuse opioids. Aquestive manufactures the sublingual film formulation of Suboxone through its sole and exclusive agreement with its licensee, Indivior Inc. (“Indivior”).

33. Suboxone tablets received FDA approval in 2002, thus losing its orphan drug exclusivity in 2009. When exclusivity was close to expiring, Indivior and Aquestive agreed to develop and market Suboxone using the Company’s PharmFilm technology, thereby allowing Indivior to effectively extend its exclusivity and retain market share against generic competitors. However, beginning in 2013, Indivior and the Company faced several lawsuits alleging that they violated antitrust laws by scheming to charge higher prices, and Indivior and its parent were criminally charged and ultimately paid \$2 billion in fines. By the end of 2017, generic tablets

gained 40% of the market share, and as of January 2021, the Company's Suboxone products held approximately 40% of the film market share.

34. With the waning demand for Suboxone film in the face of generic competition, Aquestive began developing other products for commercialization.

**B. Aquestive Develops Libervant, But Requires Additional Data to Secure FDA Approval**

35. Aquestive's most promising drug is Libervant, which the Company began developing in early 2016. Libervant is an orally administered soluble film formulation of diazepam to treat refractory epilepsy. Over 3.2 million Americans suffer from epilepsy. Every year, about 13% of these – 425,000 patients – experience cluster seizures, usually defined as 2 or 3 seizures occurring in one day.

36. Cluster seizures typically end on their own but can result in medical emergencies. The most dangerous side effect is status epilepticus, a seizure lasting 5 minutes or more. It can cause permanent injury or death if not stopped within about 30 minutes. More commonly, cluster seizures can lead to postictal psychosis, a psychotic episode that can leave patients with hallucinations and disorders of thought, which usually lasts less than a week.

37. Some patients who experience cluster seizures end up in the emergency room and are treated with diazepam, an active pharmaceutical ingredient known to halt seizure clusters. Until 2018, the only FDA-approved treatment for cluster seizures was Diastat, a rectal gel. It must be applied by a caregiver and, as a result,

presents discomfort enormous social challenges because cluster seizures can occur outside the home, away from a trained caregiver. The patient must also find a private place in which the caregiver can apply Diastat and may fear the stigma associated with others learning why the caregiver was necessary.

38. The FDA designated Libervant an orphan drug in November 2016. Soon after the Company's initial public offering in July 2018, Aquestive presented interim clinical trial results and other clinical data to the FDA.

39. During a December 2018 pre-NDA meeting, the FDA noted that Libervant's clinical trials compared it to Diastat in patients who had been fasting for 10 hours in its clinical trials, which was unlikely to be the case in the real world. As a result, the FDA informed Aquestive that data comparing Libervant and Diastat in the same patients in real world conditions would be required to support regulatory approval (the "Crossover Study").

40. The Crossover Study would compare the absorption of diazepam in patients who had just eaten. Each patient would eat a medium fat meal, and would then take either Diastat or Libervant. In the following hours and (much less frequently) days, the concentration of diazepam in the patient's blood would be measured. Then after 28 days, the patient would repeat the trial with the other product – i.e., if the patient had received Libervant the first time, the patient would

receive Diastat the second time, and vice versa. Only patients on anti-epileptic drugs could participate in the study.

41. To support regulatory approval under Section 505(b)(2) of the Food, Drug, and Cosmetic Act, Aquestive had to demonstrate Libervant was equivalent to Diastat, i.e. that patients achieved a similar concentration of diazepam in their bloodstream after taking Libervant as they achieved after taking Diastat. This was measured using three metrics: (i) the peak concentration of diazepam the patient achieved following each of Libervant and Diastat (“C<sub>max</sub>”);<sup>1</sup> time to reach C<sub>max</sub>; and area-under-curve, which takes into account both the concentration and the duration. Thus, Aquestive had to show that the C<sub>max</sub> ratio was at or about 100% to establish that Libervant and Diastat are equivalent.

42. The protocol made it clear that Aquestive understood that if there were any differences in C<sub>max</sub> between Libervant and Diastat, it would require additional consultation with the FDA:

[I]t can be expected that diazepam C<sub>max</sub> values observed in this study following a moderate-fat meal will be similar under both treatments [i.e., Diastat and Libervant]. In the event that this is not the case, Aquestive anticipates that results from this study will be used to refine

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<sup>1</sup> C<sub>max</sub> is represented as the ratio of peak concentration of diazepam after Libervant compared to peak concentration of diazepam after Diastat. For example, for a given patient, a C<sub>max</sub> ratio of 50% means that the peak concentration under Libervant was half as much as that under Diastat.

the recommended dose regimen in consultation and collaboration with the [FDA].

43. On a December 20, 2018 call immediately after the pre-NDA meeting, Barber represented that the protocol for the Crossover Study had been designed in consultation with the FDA, and implied that the FDA had approved the protocol. Defendant Barber told investors, “The [pre-NDA meeting] was a very positive meeting. There were a lot of elements of our program that were validated in that meeting, including the safety work we’ve done, including all of the PK work we’ve done to-date.” Defendant Kendall explained on the December 20, 2018 call, that Aquestive needed only to complete one additional study: “The one piece of PK bridging data we have not collected to date is Diastat data in patients under conditions of use. We will conduct a small, single-dose, crossover study versus our Libervant in order to obtain this data.” Barber assured investors that “from our perspective, the FDA gave us verbal indication that we are very, very close and this is the end of the process.”

**C. Unbeknownst to Stockholders, The Crossover Study Shows Libervant May Not Be Equivalent To Diastat**

44. Of the 28 patients in the Crossover Study, five (18%) did not reach sufficient peak concentration when taking Libervant as compared to Diastat. Their C<sub>max</sub> ratios averaged about 50%, meaning that their peak concentration of diazepam under Libervant was only half as much as that under Diastat.

45. As a result, Libervant was not as effective as Diastat for approximately one out of five subjects, and thus there was a very real possibility that the FDA would find that Libervant is not equivalent to Diastat. As such, there was a substantial risk that Libervant would not be able to rely on Diastat to demonstrate that it was safe and effective, and the FDA would reject its NDA and require additional studies at different dosage levels.

**D. The Individual Defendants Caused Aquestive To Make Misleading Statements**

46. On August 6, 2019, the Individual Defendants caused the Company to announce “positive topline results” from the Crossover Study in a press release that stated: “Diazepam exposure following the buccal film was *comparable* to the rectal gel as assessed by maximal plasma concentration.” It further stated that “[a]cross the four weight classes, buccal film demonstrated more consistent Cmax values than was observed in this study for rectal gel.”<sup>2</sup>

47. The same day, the Individual Defendants caused the Company to issue a press release which announced Q2 2019 financial results and stated:

The Company reported positive topline data from the single dose crossover study, which compared the pharmacokinetic responses in a common set of patients receiving a dose of Libervant™ (diazepam) Buccal Film and a dose of diazepam rectal gel. Preliminary analyses show that the overall diazepam exposure achieved from the buccal film was the same as for gel based on the patient dosing algorithm and there

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<sup>2</sup> Unless otherwise stated, all emphasis in bold and italics hereinafter is added.



was no difference between buccal film and gel in the effect of enzyme induction from taking concurrent anti-epileptic medications. Additionally, there were no instances of low or non-responders observed after Libervant administration, while over 10% of those same patients failed to achieve adequate exposure following gel administration.

48. On August 6, 2019, JMP issued a report describing the Crossover Study results as the “final de-risking event for the Libervant development program.”

49. The statements in ¶¶ 46-47 were materially misleading because they failed to disclose that: (a) 18% (five of twenty-eight) of patients achieved peak concentrations under Libervant that were only about 50% of what they achieved under Diastat; (b) as a result, Libervant was not as effective as Diastat; and (c) as a result, there was a substantial risk that Libervant would not be considered equivalent to Diastat to support regulatory approval.

50. On August 7, 2019, Aquestive held an earnings call to discuss the second quarter 2019 financial results. During the call, defendant Kendall misleadingly touted the results of the Crossover Study:

***We believe that we’ve met the specific requirements for approval communicated to us by the FDA.***

\* \* \*

Top line results confirmed our dosing model algorithm is appropriate for patients and will support a lower top dose than the top dose for the rectal gel. ***The results also show no difference between the film and the gel in patients*** using concurrent AED medications. In addition, once again, we observed several patients in the study who did not respond to a dose of the rectal gel, but in those same patients, we were able to produce therapeutic blood levels with Libervant.

51. On this news, the price of Aquestive's stock increased 11% (\$0.37/share) to close at \$3.52/share on August 7, 2019.

52. The statements in ¶ 50 were materially misleading because they failed to disclose that: (a) 18% (five of twenty-eight) of patients achieved peak concentrations under Libervant that were only about 50% of what they achieved under Diastat; (b) as a result, Libervant was not as effective as Diastat; and (c) as a result, there was a substantial risk that Libervant would not be considered equivalent to Diastat to support regulatory approval.

53. At the September 9, 2019, H.C. Wainwright 21st Annual Investment Conference, Maxwell stated in prepared remarks that “*every single time that we dose, in the studies that we’ve done, we’ve gotten the blood levels that we need in a clinical study.*” The slide presentation similarly stated that the Crossover Study had shown that “*Diazepam exposure following buccal film showed comparable bioavailability to rectal gel as assessed by maximal plasma concentration (C<sub>max</sub>).*” The slide added that the Crossover Study “*confirmed [the] dosing algorithm.*”

54. The statements in ¶ 53 were materially misleading because they failed to disclose that: (a) 18% (five of twenty-eight) of patients achieved peak concentrations under Libervant that were only about 50% of what they achieved under Diastat; (b) as a result, Libervant was not as effective as Diastat; and (c) as a

result, there was a substantial risk that Libervant would not be considered equivalent to Diastat to support regulatory approval.

55. On November 5, 2019, the Individual Defendants caused the Company to issue a press release announcing results for the third quarter of 2019, stating, “We successfully completed the crossover study requested by the U.S. Food and Drug Administration (FDA) for Libervant compared to the reference listed rectal gel.”

56. On December 2, 2019, the Individual Defendants caused Aquestive to issue a press release announcing that it had filed an NDA for Libervant and quoted Kendall as saying:

We are very pleased to have completed our NDA filing for Libervant as we had committed. We look forward to sharing the results from the single dose crossover study at the upcoming American Epilepsy Society 2019 Annual Meeting. ***We believe these results confirm our dosing algorithm and satisfy the final clinical requirement requested by the FDA[.]***

57. On December 9, 2019, Aquestive held a Forum and Webcast to discuss the NDA for Libervant in advance of an equity offering. Defendant Kendall stated, “we’re here to demonstrate why we believe we’ve provided the FDA with all of the appropriate data in response to the questions they had at our [December 2018] pre-NDA meeting.” Kendall added that “[a]t the end of the meeting today, I think you’ll agree ***we have the data required for approval*** to bring this highly differentiated product, Libervant, to the market[.]”

58. The statements in ¶¶ 55-57 were materially misleading because they failed to disclose that: (a) 18% (five of twenty-eight) of patients achieved peak concentrations under Libervant that were only about 50% of what they achieved under Diastat; (b) as a result, Libervant was not as effective as Diastat; and (c) as a result, there was a substantial risk that Libervant would not be considered equivalent to Diastat to support regulatory approval.

59. On March 11, 2020, the Individual Defendants caused Aquestive to file its annual report for the fiscal year ended December 31, 2019 on Form 10-K (the “2019 10-K”) with the SEC. It was signed by defendants Kendall, Maxwell, Bratton, Brown, Cochran, Costa, Lurker, and Scibetta. The 2019 10-K stated:

We believe that our product candidate Libervant is “*clinically superior*” to the two currently FDA-approved products with the same moiety and for the same indication as Libervant, as qualifying as “a major contribution to patient care” within the meaning of the FDA regulation and guidance.

60. The statements in ¶ 59 were materially misleading because they failed to disclose that: (a) 18% (five of twenty-eight) of patients achieved peak concentrations under Libervant that were only about 50% of what they achieved under Diastat; (b) as a result, Libervant was not as effective as Diastat; and (c) as a result, there was a substantial risk that Libervant would not be considered equivalent to Diastat to support regulatory approval.

**E. The Truth Emerges**

61. On September 25, 2020, after close of trading, Aquestive announced receipt of a Complete Response Letter (“CRL”) from the FDA, stating that the FDA would not approve the Libervant NDA because certain groups of patients “showed a lower drug exposure level than desired.” The FDA found that two groups of Libervant patents had Cmax levels that were too low, including 18% of patients who achieved peak concentration levels under Libervant that were only about 50% what they achieved under Diastat.

62. The same day, Aquestive held a conference call to discuss the CRL. A slide presentation for use during that conference call was filed as Ex. 99.2 to the Form 8-K filed that same day, which noted that two groups of patients “showed lower Cmax levels when compared to Diastat”, and stated that the “FDA is concerned” that the Cmax in two groups of patients was “too low” and noted that 5 of these patients “had a median Cmax level that was approximately half of the median Diastat level.”

63. Also attached as Ex. 99.3 to the Form 8-K filed September 25, 2020 were FAQs for use during the conference call which stated that the FDA indicated in the CRL that these patients had “lower absorption rates” it was seeking “an increase in exposure.”

64. Despite statements touting the data and the likelihood of approval, the FAQs revealed that the Individual Defendants were aware of the FDA's concerns about these patients' exposure levels prior to receiving the CRL, and thus the heightened risk that Libervant's NDA would be denied, stating:

[T]he Company believes, based on its *extensive dialogue with the FDA review team prior to receiving the CRL*, that its resubmitted PK modeling data showing the appropriate dosing change and increased exposure in the two identified weight ranges will be sufficient to approve the NDA for Libervant and that it will not need to conduct any further clinical studies in order to cure the deficiencies cited in the CRL[.]

\* \* \*

The Company had discussions with the FDA when the *FDA raised questions about this data* and the Company submitted additional information that it believed would respond to the Agency's questions.

Although the *FDA did not accept this additional information as dispositive*, our conversations with the Agency were constructive, and we believe these conversations support our view that we will be able move forward using our PK model-based dosing adjustments rather than conducting additional clinical trials. We will confirm this view with the FDA in our next meeting with the FDA.

65. On September 28, the next trading day, the share price of Aquestive's stock closed at \$4.97, down \$2.64 (34.6%) from its previous close of \$7.61.

## **VI. DAMAGES TO THE COMPANY**

66. As a direct and proximate result of the Individual Defendants' conduct, Aquestive has been seriously harmed and will continue to be. Such harm includes, but is not limited to:

- (a) Legal fees incurred in connection with the Securities Class Action;
- (b) Any funds paid to settle the Securities Class Action; and
- (c) Costs incurred from compensation and benefits paid to the Individual Defendants who have breached their duties to Aquestive.

67. In addition, Aquestive's business, goodwill, and reputation with its business partners, regulators, and shareholders have been gravely impaired. The Company still has not fully admitted the nature of its false statements and the true condition of its business. The credibility and motives of management are now in serious doubt.

68. The actions complained of herein have irreparably damaged Aquestive's corporate image and goodwill. For at least the foreseeable future, Aquestive will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have

misled the investing public, such that Aquestive's ability to raise equity capital or debt on favorable terms in the future is now impaired.

## **VII. DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS**

69. Plaintiff brings this action derivatively in the right and for the benefit of Aquestive to redress injuries suffered, and to be suffered, by Aquestive as a direct result of breaches of fiduciary duty by the Individual Defendants and contribution for violations of Sections 10(b) of the Exchange Act. Aquestive is named as a nominal defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

70. Plaintiff will adequately and fairly represent the interests of Aquestive in enforcing and prosecuting its rights.

71. Plaintiff has continuously been a shareholder of Aquestive at times relevant to the wrongdoing complained of and is a current Aquestive shareholder.

72. When this action was filed, Aquestive's Board consisted of defendants Kendall, Brown, Cochran, Costa, Lurker, and Scibetta and non-party directors Krop and Taglietti. Plaintiff did not make any demand on the Board to institute this action because such a demand would be a futile, wasteful, and useless act, as set forth below.



**A. Given That Libervant's Exclusivity Was Key to the Company's Future Growth, the Entire Board Attempted to Undermine A Key Competitor When The Crossover Study Failed**

73. With Suboxone in decline due to generic competition, Libervant was key to Aquestive's growth. Given that the FDA had specifically requested the Crossover Study to demonstrate Libervant was equivalent to Diastat, its results were of paramount importance to the Company, including the Cmax which is a critical parameter in any pharmacokinetic study. Given the critical need to demonstrate that Libervant was equivalent to Diastat in order to secure FDA approval, and thus Aquestive's future, it is reasonable to infer that the Individual Defendants knew or should have known of the shortfalls of the Crossover Study.

74. Additionally, it is reasonable to infer that the Individual Defendants knew that the Crossover Study failed to demonstrate that Libervant was equivalent to Diastat because, once the results were known, they took steps to slow the competition. Specifically, Aquestive's lead competitor is Neurelis Inc., ("Neurelis") whose product Valtoco would deliver diazepam intranasally. Valtoco received orphan designation one year before Libervant, and Neurelis filed its NDA for Valtoco more than a year before Aquestive filed the Libervant NDA.

75. When the Individual Defendants learned of the unfavorable results of the Crossover Study in or around August 2019, they knew Valtoco's NDA was submitted nearly a year before and was nearing an approval decision. Had the

Company sought clarification from the FDA, it would first have to request a meeting which, if approved, would not be held until months later, and would then have to wait more months to receive the meeting minutes. If the FDA were to instruct Aquestive to do further work, it would be at least six months until it could refile. Indeed, when the FDA rejected Libervant in September 2020, Aquestive did not refile until June 24, 2021.

76. Given this paradigm, after the Individual Defendants received the Crossover Study results they sought to delay FDA approval of Valtoco. On November 1, 2019, approximately one month before Aquestive filed the Libervant NDA, Aquestive filed a Citizen Petition requesting that the FDA stay approval of Valtoco until Neurelis completed an additional study. The FDA denied the Citizen Petition on January 10, 2020, the same day it approved Valtoco, and noted that it was likely an effort to delay Valtoco's approval rather than to raise substantive concerns.

77. Even prior to the Crossover Study, the Individual Defendants sought a "strategic partnership" with Neurelis beginning as early as June 2017. However, according to documents filed in *Neurelis, Inc. v. Aquestive Therapeutics, Inc.*, Case No. 37-2019-646650CU-BT-CTL (Cal. Sup. Ct. San Diego), this was merely an attempt to take out the competition. Over the next several years, Aquestive's management solicited meetings with Neurelis's leadership to garner a partnership,

which were summarily denied. Knowing the risk that a failed Crossover Study would require additional studies and allow Valtoco to Libervant to market and gain exclusivity, defendants Kendall and Barber demanded that Neurelis agree to “work together” with Aquestive, threatening to invalidate Neurelis’s patents which would undermine Valtoco’s exclusivity.

78. Given the lengths to which the Individual Defendants went to stifle Neurelis after the Crossover Study results were released, it is reasonable to infer that the Individual Defendants knew that the results were inadequate to support regulatory approval. They face a substantial likelihood of liability for failing to disclose the same and allowing the misleading statements to continue.

**B. Additional Reasons That Demand is Excused**

79. Kendall is the Company’s CEO and a director, and therefore, is not independent. As an employee, Kendall derives substantially all of his income from his employment with Aquestive, thus could not disinterestedly consider a demand for action that might require him to sue the directors that control his continued employment and/or fellow members of management with whom he works on a day-to-day basis. Moreover, as CEO and as alleged herein, Kendall is named as a defendant in the Securities Class Action and made or was responsible for issuing materially misleading statements at issue. As a result, Kendall would be interested in a demand regarding his own wrongdoing and demand is futile as to him.

80. Furthermore, Brown, Lurker, and Scibetta served as members of the Audit Committee at relevant times, as such they are responsible for the integrity of the Company's financial risk management and the adequacy of its disclosure controls. Thus, Brown, Lurker, and Scibetta knew or should have known of the failed Crossover Study because it presented a substantial risk that the Libervant NDA would not be approved, which in turn presented a financial risk to Aquestive's future. Moreover, in their capacities as Audit Committee members, Brown, Lurker and Scibetta reviewed and approved the Company's earnings press releases, allowing the materially misleading statements to be disseminated in Aquestive's SEC filings and other disclosures. Thus Brown, Lurker, and Scibetta have breached their fiduciary duties and are not disinterested, and demand is excused as to them.

81. Kendall, Brown, Cochran, Lurker, and Scibetta also served on the Disclosure Committee, as such they are responsible for public disclosures made by the Company to the SEC and the Company's stockholders. In their capacities as members of the Disclosure Committee, Kendall, Brown, Cochran, Lurker, and Scibetta reviewed and approved the public disclosures, allowing the materially misleading statements to be disseminated. Thus Kendall, Brown, Cochran, Lurker, and Scibetta have breached their fiduciary duties and are not disinterested, and demand is excused as to them.

## **VIII. CLAIMS FOR RELIEF**

### **Count I**

#### **(Against the Individual Defendants for Breach of Fiduciary Duty)**

82. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

83. Each Individual Defendant owes and owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of Aquestive's business and affairs, particularly with respect to issues as fundamental as public disclosures.

84. The Individual Defendants' conduct set forth herein was due to their intentional or reckless breach of the fiduciary duties they owed to the Company. The Individual Defendants intentionally or recklessly breached or disregarded their fiduciary duties to protect the rights and interests of Aquestive.

85. In breach of their fiduciary duties owed to Aquestive, the Individual Defendants willfully participated in and caused the Company to expend unnecessarily its corporate funds, rendering them personally liable to the Company for breaching their fiduciary duties.

86. In particular, the Individual Defendants knowingly or recklessly made untrue statements and/or permitted the Company's public filings, disclosures, and statements to misleadingly report the Company's overall prospects.

87. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Aquestive has sustained and continues to sustain significant damages. Including direct monetary damages, exposure to liability from securities litigation and a loss of goodwill in the capital markets. As a result of the misconduct alleged herein, Individual Defendants are liable to the Company.

### **Count II**

#### **(Against Defendants Kendall, Maxwell, and Barber for Contribution For Violations of Sections 10(b) and 21D of the Exchange Act)**

88. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

89. The conduct of Defendants Kendall, Maxwell, and Barber, as described herein, has exposed the Company to significant liability under various federal and state securities laws by their disloyal acts.

90. Aquestive is named as a defendant in a related securities fraud lawsuit that alleges and asserts claims arising under Section 10(b) of the Exchange Act. The Company is alleged to be liable to private persons, entities and/or classes by virtue of many of the same facts alleged herein. If Aquestive is found liable for violating the federal securities laws, the Company's liability will arise in whole or in part from the intentional, knowing, or reckless acts or omissions of all or some of the Defendants as alleged herein, who have caused the Company to suffer substantial harm through their disloyal acts. The Company is entitled to contribution and

indemnification from these Defendants in connection with all claims that have been, are, or may be asserted against the Company by virtue of their wrongdoing.

91. As officers, directors and otherwise, Defendants Kendall, Maxwell, and Barber had the power or ability to, and did, control or influence, either directly or indirectly, Aquestive's general affairs, including the content of its public statements, and had the power or ability to directly or indirectly control or influence the specific corporate statements and conduct that violated Section 10(b) of the Exchange Act and SEC Rule 10b-5.

92. Defendants Kendall, Maxwell, and Barber are liable under Section 21D of the Exchange Act, which governs the application of any private right of action for contribution asserted pursuant to the Exchange Act.

93. Defendants Kendall, Maxwell, and Barber have damaged the Company and are liable to the Company for contribution.

94. No adequate remedy at law exists for Plaintiff by and on behalf of the Company.

## **IX. PRAYER FOR RELIEF**

WHEREFORE, plaintiff, on behalf of Aquestive, demands judgment as follows:

A. Declaring that plaintiff may maintain this action on behalf of Aquestive and that plaintiff is an adequate representative of the Company;

B. Against all of the Individual Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the Individual Defendants' breaches of fiduciary duties and other wrongs;

C. Declaring that the Individual Defendants have breached their fiduciary duties to Aquestive;

D. Directing Aquestive to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect Aquestive and its stockholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for stockholder vote, resolutions for amendments to the Company's Bylaws or Articles of Incorporation and taking such other action as may be necessary to place before stockholders for a vote of the following corporate governance policies:

1. a proposal to strengthen the Company's controls over financial reporting;

2. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater stockholder input into the policies and guidelines of the Board;

3. a proposal to strengthen Aquestive's oversight of its disclosure procedures; and



4. a provision to permit the stockholders of Aquestive to nominate at least three candidates for election to the Board;

E. Awarding to Aquestive restitution from Individual Defendants, and each of them, and ordering disgorgement of all profits, benefits, and other compensation obtained by the Individual Defendants;

F. Awarding to plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

G. Granting such other and further relief as the Court deems just and proper.

#### **X. JURY DEMAND**

Pursuant to Fed. R. Civ. P. 38(b), plaintiff hereby demands a trial by jury.

Dated: December 15, 2021

/s/ Lisa J. Rodriguez

**SCHNADER HARRISON SEGAL &  
LEWIS LLP**

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Telephone: (215) 638-4847


*Counsel for Plaintiff Loreen Niewenhuis*

### **VERIFICATION**

I, Loreen Niewenhuis, do hereby verify that I am a holder of common stock of Aquestive Therapeutics, Inc., and was a holder of such common stock at the time of the wrongs complained of in the foregoing Verified Shareholder Derivative Complaint (“Complaint”). I have authorized the filing of the Complaint. I have reviewed the Complaint. All of the averments contained in the Complaint regarding me are true and correct upon my personal knowledge and, with respect to the remainder of the averments, are true and correct to the best of my knowledge, information, and belief.

I declare under penalty of perjury that the foregoing is true and correct.

Date: 12/9/2021

DocuSigned by:  
  
AEC912E72BEA436...

Loreen Niewenhuis

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

**I. (a) PLAINTIFFS**

(b) County of Residence of First Listed Plaintiff \_\_\_\_\_  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

**DEFENDANTS**

County of Residence of First Listed Defendant \_\_\_\_\_  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question  
(U.S. Government Not a Party)
- ☐ 4 Diversity  
(Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                        | DEF                        |   | PTF                        | DEF                        |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State                | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice <b>PERSONAL INJURY</b> <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutional of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education <b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

**V. ORIGIN** (Place an "X" in One Box Only)

- ☐ 1 Original Proceeding    ☐ 2 Removed from State Court    ☐ 3 Remanded from Appellate Court    ☐ 4 Reinstated or Reopened    ☐ 5 Transferred from Another District (specify)    ☐ 6 Multidistrict Litigation - Transfer    ☐ 8 Multidistrict Litigation - Direct File

**VI. CAUSE OF ACTION**

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

Brief description of cause:

**VII. REQUESTED IN COMPLAINT:**

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☐ No

**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE

DOCKET NUMBER

DATE

SIGNATURE OF ATTORNEY OF RECORD

**FOR OFFICE USE ONLY**

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

## INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

### Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
  - (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
  - (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
- United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
- United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
- Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
- Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
- Original Proceedings. (1) Cases which originate in the United States district courts.
- Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
- Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
- Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
- Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
- Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
- Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
- PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
- Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
- Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

**Date and Attorney Signature.** Date and sign the civil cover sheet.